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Ophthalmic instruments — Direct ophthalmoscopes

Instruments ophtalmiques — Ophtalmoscopes directs

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 10942:2006), which has been technically revised.

The main changes compared to the previous edition are as follows:

— revision of the dated references;

— editorial update of the whole document.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Ophthalmic instruments — Direct ophthalmoscopes

1 Scope

This document, together with ISO 15004-1 and ISO 15004-2, specifies minimum requirements and test methods for hand-held direct ophthalmoscopes designed for directly observing the eye fundus.

This document takes precedence over ISO 15004-1 and ISO 15004-2, if differences exist.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15004-1, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

ISO 15004-2, *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
ophthalmoscope
optical instrument used to examine the external and internal parts of the eye, particularly the media and the fundus

3.2
direct ophthalmoscope
ophthalmoscope (3.1) which provides an illuminating system, an observation system and viewing lenses which allow the observer to visualize the patient's eye directly, that is without the formation of an intermediate image

3.3
viewing lens
lens which is positioned between the observer's eye(s) and the eye to be examined in order to achieve optimum focus, i.e. to correct for patient's and/or observer's refractive error and/or accommodation

Note 1 to entry: In direct ophthalmoscopes when a selection of such lenses is required, these are integrated with or mounted in a disc or other mechanical means by which the user can easily position the lens of choice centrally in the visual path.

3.4
auxiliary lens
additional *viewing lens* (3.3) to facilitate access to higher refractive powers without requiring an excessive number of lenses

Note 1 to entry: Auxiliary lenses are normally integral with or mounted on a separate disc or other mechanical means and when required are used in conjunction with the viewing lenses.

3.5
ophthalmoscope graticule
pattern or target or graticule which can be optionally positioned in the illuminating light path within the instrument and which will be imaged on the retina for diagnostic, measurement or therapeutic purposes

Note 1 to entry: These can be fixed or focusable.

3.6
illuminating system
light source and associated lenses, mirrors and/or prism which serve to provide and project light into or onto the patient's eye

3.7
viewing system
lenses and apertures which enable the observer to examine the patient's eye

3.8
field of view
angular field which is visible when the entrance pupil is 12 mm behind the back surface of the *ophthalmoscope* (3.1), measured from the centre of the entrance pupil

Note 1 to entry: See 6.2.3 and Figure 1.

3.9
field of illumination
angular field which is illuminated and which is measured with its apex positioned at the image of the light source

4 Classification

Direct ophthalmoscopes shall be classified as follows:

a) Group A: Direct ophthalmoscopes that comply with all the requirements of this document.

b) Group B: Direct ophthalmoscopes that comply with the reduced requirements specified in Table 1 and all other requirements specified in this document except those in 5.4.2 and 5.4.3.

5 Requirements

5.1 General

The direct ophthalmoscope shall conform to the requirements specified in ISO 15004-1.

The direct ophthalmoscope shall conform to the specific requirements specified in 5.2 to 5.5.

These requirements shall be verified as specified in Clause 6.

5.2 Optical requirements

The requirements specified in Table 1 and Table 2 shall apply.

Table 1 — Requirements for optical specifications

Criterion	Requirements	
	Group A	Group B
Steps for the powers, in dioptres, of viewing lenses	0, +1, +2, +3, +4, +6, +8, +10, +15, +20, −1, −2, −3, −4, −6, −8, −10, −15, −20	10 steps in the range +10 to 0 to −10
Angle of field of view, φ	≥3°	≥2,5°
Angle of field of illumination at maximum aperture	≥9°	≥7°
Diameter of the viewing system	≥3 mm	≥2,5 mm

Table 2 — Requirements for optical accuracy

Criterion	Combined refractive power	Tolerance
Accuracy of combined refractive power (viewing lens and auxiliary lens)	0 D to +3 D 0 D to −3 D	±0,37 D
	> +3 D to +10 D < −3 D to −10 D	±0,50 D
	> +10 D to +15 D < −10 D to −15 D	±0,75 D
	> +15 D < −15 D	±1,00 D
Viewing lens centration	0 D to +10 D 0 D to −10 D	1,0 mm
	> +10 D < −10 D	0,5 mm

5.3 Construction and function of the viewing system

5.3.1 The viewing lenses shall be arranged so that, as viewed from the observer's side:

a) increments of positive power, indicated by black or green figures, increase when the disc is turned clockwise;

b) increments of negative power, indicated by red figures, increase when the disc is turned anticlockwise.

5.3.2 The viewing lens control shall be provided with indexing stops for each lens power.

5.3.3 Left-hand and right-hand operation of the viewing lens control shall be possible.

5.4 Construction and function of the illumination system

5.4.1 The defocused illumination beam shall be homogenous and achromatic as determined by visual inspection.

5.4.2 The minimum adjustment range of the luminous flux from the illuminating system of Group A direct ophthalmoscopes shall be from the maximum to 10 % of the maximum.

5.4.3 Group A direct ophthalmoscopes shall have a minimum of two aperture stops in the illuminating system. These shall be a full aperture and a reduced aperture. Additionally a red-free filter shall be included.

NOTE Other filters, apertures, ophtalmoscope graticules, slits or half-circles are optional.

5.5 Optical radiation hazard with direct ophthalmoscopes

This clause replaces IEC 60601-1:2005+A1:2012, 10.4, 10.5, 10.6 and 10.7

The direct ophthalmoscope shall conform to the relevant requirements in accordance with ISO 15004-2.

6 Test methods

6.1 General

All tests described in this document are type tests.

6.2 Checking the optical and functional requirements

6.2.1 The requirements specified in 5.2 shall be verified by the use of measuring devices with accuracy better than 10 % of the smallest value to be determined.

Measurements shall be carried out according to general rules of statistical evaluation.

For measuring the refractive power according to Table 2, a focimeter as specified in ISO 8598-1 should be used.

6.2.2 For measuring the field of view, place the direct ophthalmoscope so that the back surface of the instrument is 12 mm in front of a pin-hole illuminated by a non-collimated light source.

6.2.3 The requirements described in 5.3 and 5.4.1 shall be checked by observation.

It is essential that the divergent angle of the light source exceed the minimum angle of field of view specified in Table 1.

Project the light patch onto a screen at a distance l (expressed in millimetres) from the pin-hole (see Figure 1). Measure the diameter d (expressed in millimetres) of the fully illuminated, central core of the patch, disregarding the penumbra rim.

For the purposes of this measurement, use a 0,2 mm diameter pin-hole and calculate the angle of field of view, φ, from Formula (1):

$$\varphi = 2\tan^{-1}\left(\frac{d-0,2}{2l}\right) \tag{1}$$

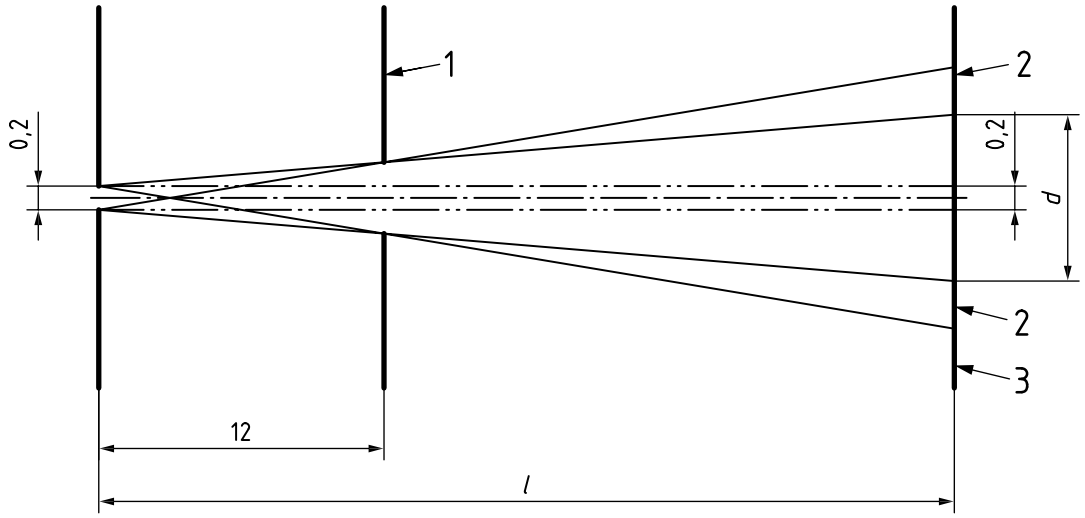
where

d is the diameter, expressed in millimetres, of the fully illuminated, central core of the patch, disregarding the penumbra rim;

l is the distance, expressed in millimetres, from the pin-hole to the screen.

If the projected light patch has a shape other than circular, the diameter d of the smallest circle which will circumscribe the projected light patch is taken as the diameter d.

Dimensions in millimetres



Key

1 back surface of ophthalmoscope
2 penumbra rim
3 screen
d diameter of the fully illuminated, central core of the patch
l distance from the pin-hole to the screen

Figure 1 — Test configuration for measuring the field of view

7 Accompanying documents

The direct ophthalmoscope shall be accompanied by documents containing instructions for use. In particular this information shall contain:

a) the name and address of the manufacturer;

b) any additional information as specified in IEC 60601-1:2005+A1:2012, 7.9;

c) a reference to this document (ISO 10942:2022), if the manufacturer or supplier claims compliance with it.

8 Marking

The direct ophthalmoscope shall be permanently marked with at least the following information:

a) the name or trade name and full address of the manufacturer;

b) where applicable, an authorized representative within the locale;

c) a distinctive identification i.e. commercial product name, model number or catalogue number;

d) the classification according to Clause 4;

e) marking as required by IEC 60601-1.

Bibliography

[1] ISO 8598-1, *Optics and optical instruments — Focimeters — Part 1: General purpose instruments*